

**THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appellant(s): Berger, A., et al.
Appl. No.: 10/089,658
Conf. No.: 6858
Filed: July 22, 2002
Title: NUTRITIONAL COMPOSITION
Art Unit: 1615
Examiner: N.G. Ebrahim
Docket No.: 0112843-00044

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' REPLY BRIEF

Sir:

I. INTRODUCTION

Appellants submit Appellants' Reply Brief in response to the Examiner's Answer dated June 4, 2009 pursuant to 37 C.F.R. § 41.41(a). Appellants respectfully submit that the Examiner's Answer has failed to remedy the deficiencies with respect to the final Office Action dated March 25, 2008, as noted in Appellants' Appeal Brief filed on December 18, 2008, for at least the reasons set forth below. Accordingly, Appellants respectfully request that the rejections of pending Claims 1, 3-11, 13-16 and 18-22 be reversed.

II. THE REJECTION OF CLAIMS 1, 3-11 AND 13 UNDER 35 U.S.C. §103(A) TO *DI MARZO* IN VIEW OF *BURCH* SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS WITH RESPECT TO THE PENDING CLAIMS

Appellants respectfully request that the Board reverse the obviousness rejection of Claims 1, 3-11 and 13 because the Examiner has still failed to establish that the pending claims are obvious in view of *Di Marzo* taken with *Burch*. Specifically, Appellants submit that (1) the skilled artisan would have no reason to combine the cited references because the cited references are directed to unrelated compositions utilizing different ingredients for different objectives, (2) the addictive effects of oxycodone is not a sufficient reason to replace oxycodone with an anandamide precursor, and (3) the Examiner is applying hindsight reconstruction and has failed to set forth sufficient reasons for how the skilled artisan would arrive at the claimed invention in view of the cited references.

1. Contrary to the Examiner's assertion, one having skill in the art would have no reason to combine *Di Marzo* with *Burch*

In the Examiner's Answer, the Examiner continues to assert that the cited references are combinable because anandamide derivatives and precursors do not have the addictive characteristics of oxycodone and *Burch* teaches generally that combinations of analgesic drugs cause synergism of its analgesic effect. See, Examiner's Answer, page 7, lines 11-13 and 20-22. The Examiner also asserts that the different mechanisms of action between oxycodone and anandamide are "not a concern in such combination" and that "the combination of NSAID's and oxycodone or anandamide is the real concern." See, Examiner's Answer, page 7, lines 13-18. Appellants respectfully disagree and submit that, absent any hindsight reconstruction, one skilled in the art would have no reason to replace the oxycodone in the composition of *Burch* with the anandamide precursor allegedly taught in *Di Marzo*.

For a combination of references to be proper under 35 U.S.C. §103(a), the skilled artisan must have had a reason to combine the two references. Such a reason is not present in the instant case because oxycodone is an entirely different compound having entirely different properties

and characteristics when compared to ananadamide precursors. As is known by those skilled in the art, opioid analgetics and antimimetics (ananadamide) comprise pharmaceutically different effective groups characterized by different mechanisms of action. The two systems not only bring about different side effects both in terms of quality and quantity, but also utilize different ligands and receptors in the respective mechanisms of action. The differences between opioid analgetics and antimimetics (anandamide) are discussed at length in Appellants' Appeal Brief.

Thus, Appellants submit that the differences between the characteristics and properties of oxycodone and anandamide are absolutely of concern here because replacing one of the compounds with the other will not affect the consumer in the same way, nor will the side effects be the same, nor will the same results necessarily occur. Indeed, based on the mechanisms of action, side effects and receptors used in the mechanisms of oxycodone metabolism, the skilled artisan, upon review of *Di Marzo* and *Burch*, would be lead down a path divergent from the presently claimed subject matter, which includes the use of an anandamide precursor that is metabolized in a completely different way when compared to oxycodone. Therefore, based on the disclosures of *Di Marzo* and *Burch*, one skilled in the art would have no reason to replace oxycodone (an opioid analgetic) with an anandamide derivative to arrive at the present claims.

2. Contrary to the Examiner's assertion, the addictive effects of oxycodone is not sufficient reason to replace oxycodone with an anandamide precursor

In the Examiner's Answer, the Examiner further asserts that “[t]he office action was clear regarding addictive effects of oxycodone and expresses clearly that this is good motivation to a person having ordinary skill in the art to replace oxycodone with an anandamide precursor to avoid addiction and side effects.” See, Examiner's Answer, page 8, lines 8-10. Appellants respectfully disagree for at least the reasons below.

As discussed at length in Appellants' Appeal Brief, opioid analgetics and antimimetics (ananadamide) comprise pharmaceutically different effective groups characterized by different mechanisms of action. The two systems not only bring about different side effects both in terms of quality and quantity, but also utilize different ligands and receptors in the respective mechanisms of action. Because of these differences, the skilled artisan would not expect compositions having oxycodone to affect a consumer in the same way as compositions with an

anandamide precursor. Accordingly, the addictive effects of oxycodone would not be enough reason to replace oxycodone with an anandamide precursor when the skilled artisan would not have expected such a replacement to achieve the same results.

Further, *Burch* discusses at length the benefits and advantages of the combination of oxycodone and rofecoxib and does not offer any substitutes for oxycodone in the composition. Specifically, *Burch* discloses that administering to a patient a combination of a dose of rofecoxib and a dose of oxycodone such that the dosing interval of the rofecoxib overlaps with the dosing interval of the oxycodone results in an analgesic effect in a human patient. See, *Burch*, Abstract. Accordingly, the skilled artisan would not have found it necessary to replace the oxycodone of *Burch*. Thus, the skilled artisan would not have any reason to combine *Burch* with *Di Marzo* absent any hindsight reconstruction.

3. Contrary to the Examiner's assertion, the skilled artisan would not have combined *Di Marzo* and *Burch* absent a hindsight reconstruction

In the Examiner's Answer, the Examiner asserts that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. The Examiner further asserts that "so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper." See, Examiner's Answer, page 8, line 21-page 9, line 1. However, as noted above, *Burch* discusses at length the benefits and advantages of the combination of oxycodone and rofecoxib and does not offer any substitutes for oxycodone in the composition. Accordingly, the skilled artisan would not have found it necessary to replace the oxycodone of *Burch*. Thus, the skilled artisan would not have any reason to combine *Burch* with *Di Marzo* absent any hindsight reconstruction.

Further, since *Burch* discloses the benefits and advantages of the combination of oxycodone and rofecoxib and does not offer any substitutes for oxycodone in the composition, *Burch* teaches away from the replacement of oxycodone with an anandamide precursor as is required in the present claims. For the above reasons, Appellants respectfully submit that the cited references are not combinable because they are directed toward completely different products with completely different objectives.

Accordingly, for at least the reasons discussed above, Appellants respectfully submit that Claims 1, 3-11 and 13 are novel, nonobvious and distinguishable from the cited references and are in condition for allowance.

III. THE REJECTION OF CLAIMS 14-16 AND 18-22 UNDER 35 U.S.C. §103(A) TO *DI MARZO* IN VIEW OF *BURCH* AND FURTHER IN VIEW OF *KYLE* SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS WITH RESPECT TO THE PENDING CLAIMS

Appellants respectfully request that the Board reverse the obviousness rejection of Claims 14-16 and 18-22 because the Examiner has still failed to establish that the pending claims are obvious in view of *Di Marzo* taken with *Burch* and further in view of *Kyle*. Specifically, Appellants submit that (1) *Kyle* fails to remedy the deficiencies of *Di Marzo* and *Burch*, and (2) the Examiner is applying hindsight reconstruction and has failed to set forth sufficient reasons for how the skilled artisan would arrive at the claimed invention in view of the cited references.

1. Contrary to the Examiner's assertion, *Kyle* fails to remedy the deficiencies of *Di Marzo* with *Burch*

In the Examiner's Answer, the Examiner continues to assert that *Kyle* discloses that ARA is one of the compounds comprised by the precursor in the Markush group recited in the instant claims where the structure includes 20-carbon chain and four *cis* double bonds. See, Examiner's Answer, page 8, lines 18-20. However, Appellants note that such a disclosure still fails to remedy the deficiencies of *Di Marzo* and *Burch*, as discussed at length in Appellants' Appeal Brief. Specifically, the skilled artisan would still have no reason to combine *Di Marzo* and *Burch* to arrive at the present claims. Accordingly, *Kyle* fails to remedy the deficiencies of *Di Marzo* and *Burch*.

2. Contrary to the Examiner's assertion, the skilled artisan would not have combined *Di Marzo*, *Burch* and *Kyle* absent a hindsight reconstruction

In the Examiner's Answer, the Examiner asserts that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. The Examiner further asserts that "so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper." See, Examiner's Answer, page 8, line 21-page 9, line 1. For at least the reasons discussed above with respect to *Di Marzo* and *Burch*, the skilled artisan would not have any reason to combine *Kyle* and *Burch* with *Di Marzo* absent any hindsight reconstruction.

Accordingly, for at least the reasons discussed above, Appellants respectfully submit that Claims 14-16 and 18-22 are novel, nonobvious and distinguishable from the cited references and are in condition for allowance.

IV. CONCLUSION

Appellants submit that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103(a) with respect to the rejection of Claims 1, 3-11, 13-16 and 18-22. Accordingly, Appellants respectfully submit that the obviousness rejection is erroneous in law, and in fact, and therefore should be reversed by this Board.

The Director is authorized to charge any other fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal occurs, please indicate the Attorney Docket No. 0112843-00044 on the account statement.

Respectfully submitted,

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